



Dkt. 0575/61545/JPW/PJP/PL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#15

Applicants: Reba Goodman, et al

U.S. Serial No.: 09/769,902 Examiner: D. Sullivan

Filed: January 25, 2001 Group Art Unit: 1636

For: A METHOD FOR REGULATING GENES WITH  
ELECTROMAGNETIC RESPONSE ELEMENTS

1185 Ave of the Americas  
New York, New York 10036

Assistant Commissioner of Patents  
Washington, D.C. 20231

Sir:

DECLARATION OF MARTIN BLANK TO 37 C.F.R. §1.132

I, Martin Blank, hereby declare as follows:

1. I am one of the inventors of the subject matter claimed in the above-identified patent application.
2. I am an Associate Professor of Physiology and Cellular Biophysics at Columbia University, the assignee of record of the subject invention. I hold Ph.D.'s in physical chemistry and colloid science. A copy of my curriculum vitae is attached hereto as **Exhibit 2**.
3. I have reviewed the Office Action issued by the United States Patent and Trademark Office on February 24, 2003 wherein the pending claims 1-12 directed to a method comprising introducing electromagnetic response

Applicants: Reba Goodman, et al.  
U.S. Serial No.: 09/769,902  
Filing Date: January 25, 2001  
Exhibit 1

Applicants: Reba Goodman, et al  
U.S. Serial No. 09/769,902  
Filed: January 25, 20

Page 2

elements into a gene promoter not having any electromagnetic field response elements and applying an electromagnetic field to induce gene expression in a subject were rejected as being allegedly not enabled by the specification of the subject application. I have additionally reviewed the subject application.

4. I understand that pending claims 1-12 are being rejected because the Examiner alleged that a skilled artisan would not predict a therapeutic effect resulting from a method comprising introducing electromagnetic response elements into a gene promoter not having any electromagnetic field response elements and applying an electromagnetic field to induce gene expression to a subject based on the teachings of the prior art and instant disclosure without engaging in undue experimentation.
5. I believe that, without undue experimentation, someone of ordinary skill in the art as of the January 25, 2001 filing date, following only the disclosure of the subject application and other information publicly available at that time, could conduct a working *in vivo* experiment to practice the claimed invention of introducing electromagnetic response elements into a gene promoter not having any electromagnetic field response elements and applying an electromagnetic field to induce gene expression in a subject with sustained therapeutic results.

Applicants: Reba Goodman, et al  
U.S. Serial No. 09/769,902  
Filed: January 25, 2001  
Page 3

6. One way of performing the experiment would be first to incorporate the electromagnetic response elements (EMREs) in promoters of any gene for regulating activation of that gene. For example, an exogenous insulin gene containing one or more EMREs inserted upstream of the gene, can be simply and safely regulated by the EM fields. The EMRE containing gene can be introduced clinically into a subject using such standard methods as electroporation. The regulation of the gene can be made automatic by having an exogenous EM field generating circuit activated by an implanted glucose sensor that responds immediately to changes in pre-set blood glucose levels. I believe that this experiment would not require undue experimentation and has a reasonable expectation of success.

7. I hereby declare that all statements made herein on my own knowledge are true and that all statements made herein on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

April 29, 2003  
Date

Martin Blank  
Martin Blank, Ph.D.